

K960507

**510(K) SUMMARY FOR STAR DENTAL
PUSHBUTTON AUTOCHUCK REPLACEMENT TURBINE**

Company:

Star Dental, Division of Den-Tal-Ez, Inc.

CONFIDENTIAL

Contact Person:

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Device Trade Name:

Star Dental Pushbutton Autochuck Replacement Turbine.

Common or Usual Name:

Replacement Turbine

Predicate Device(s):

Midwest Quiet-Air and Tradition model handpieces.
Star Dental 430 series pushbutton autochuck turbine

Description/Intended Use:

Both the predicate turbines and the proposed Star Dental replacement turbines are intended to be used as components to high speed handpieces, which are used intraorally by trained dental professionals for drilling and preparation of dental cavities for restoration, such as fillings.

Substantial Equivalence:

Both the predicate and the proposed Star Dental replacement turbines utilize the same technology, similar turbine design, manufacturing practices and materials. Substantial equivalence is achieved based on similarity in design and intended use.